

Abstracts

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instrument and the Skindex-29 questionnaire appear to have reasonable performance and validity for ChHD patients. Further validation studies with a larger sample size will be needed to confirm these findings.

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IMPROVED HEALTH-RELATED QUALITY OF LIFE FOLLOWING SUSTAINED REDUCTIONS IN ANTI DS-DNA ANTIBODYS [ÁDSDNA AB] IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AFTER TREATMENT WITH LJP394

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OBJECTIVE: Treatment with LJP 394 results in decreased ÁdsDNA Ab in patients with SLE. Sustained reductions were demonstrated in 2 RCTs of 298 [phase 3] and 189 [phase 2/3] SLE patients with a history of renal disease, statistically favoring active vs placebo treatment. SF-36 was assessed at baseline, 6 and 12 months in phase 3 to evaluate the impact of sustained reductions on patient reported HRQOL. **METHODS:** Sustained reductions: $\geq 20\%$ decreases from baseline in $\geq 2/3$ of all ÁdsDNA Ab determinations defined “responders”. Minimal clinically important differences [MCID] were based on a 15-point global change scale. **RESULTS:** In phase 3, 31.4% patients were responders, 63 in LJP394, 28 in placebo; a ratio of 2.25 favoring active treatment. At 6 months, 31.3% were responders: 59 LJP394 and 27 placebo; a ratio of 2.2. At 6 months, responders reported improvement in all domains of SF-36 with the largest increases in bodily pain (8.2), vitality (8.0), general health perceptions (6.6) and physical function (5.7). Non-responders reported worsening in all but 3 domains, which remained unchanged (vitality (1.3), mental health (0.9), and role emotional (0.0)). At 12 months, 43 LJP394 and 24 placebo treated patients were responders; a ratio of 1.8; 35.3% overall. Improvements reported by responders increased by month 12, with largest changes in role physical (13.8), vitality (10.2), general health profile (9.3), and bodily pain (7.3), again with no change or deterioration in non-responders. Improvements in domain scores were reflected in physical component summary [PCS] score. MCID was determined to range from 6.7 to 11.4 points in domain and 3.4 to 3.9 in PCS scores, consistent with literature reported estimates of 5–10 and 2.5–5.0 points. **CONCLUSION:** Sustained reductions in ÁdsDNA Ab levels lead to improvement in patient reported HRQOL. These improvements are clinically meaningful, regardless of treatment group. LJP394 administration resulted in 1.8 to 4.0 times more responders than placebo.

EARS/EYES/SKIN**EARS/EYES/SKIN—Health Policy Studies****PES18**

THE IMPACT OF THE SYSTEM TO MANAGE ACCUTANE-RELATED TERATOGENICITY™ (SMART™) RISK MANAGEMENT PROGRAM ON ISOTRETINOIN PRESCRIBING TRENDS

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OBJECTIVE: To describe an evaluation of isotretinoin prescribing patterns before and after implementation of the System to Manage Accutane-Related Teratogenicity (SMART), a risk management plan developed by Hoffmann-LaRoche to minimize the risk of pregnancy among women taking Accutane. **METHODS:** The IMS Health, National Prescription Audit Plus provided information on the number of prescriptions dispensed for the

pre- (1 April 2001–31 March 2002) and post- (1 April 2002–31 March 2003) SMART periods. Data on patient gender, prescriber speciality, and physician-reported severity of indication for use were obtained from AdvancePCS, a large pharmacy benefits manager (PBM), and the IMS Health, National Disease and Therapeutic Index. **RESULTS:** In the 12-months prior to SMART, 1,508,000 prescriptions were dispensed for isotretinoin; declining approximately 23% to 1,160,000 prescriptions in the year following SMART. Dermatologists were the most common prescribers of isotretinoin, accounting for 76% and 80% of the prescriptions dispensed in the year before and after SMART, respectively. Half of the claims for isotretinoin were for females in both the pre- and post-SMART eras. The severity of indication for use did not appear to be affected by SMART. In the year pre-SMART, 53% of the isotretinoin mentions during office visits for female patients were for “severe” acne cases, compared to 55% in the year post-SMART. Similar percentages were seen for males. **CONCLUSIONS:** SMART may have influenced the number of isotretinoin prescriptions dispensed, but appeared to have little impact on other variables such as prescriber speciality and severity of indication for use.

MENTAL HEALTH**MENTAL HEALTH—Clinical Outcomes Studies****PMH1**

EFFECT OF ZIPRASIDONE INITIAL DOSING ON DISCONTINUATION IN SCHIZOPHRENIA

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OBJECTIVES: To examine the effects of initial ziprasidone dose on discontinuation rates, using the PharMetrics integrated medical and pharmacy claims data. **METHODS:** Patients ≥ 18 years with a diagnosis of schizophrenia and a ziprasidone claim between March 2001 and February 2003 continuously enrolled for ≥ 6 months before and ≥ 3 months after initiation of ziprasidone were stratified by initial daily dose (≥ 40 mg and < 80 mg [low] vs. ≥ 80 mg and < 120 mg [medium] vs. 120mg–160mg [high]). The 6-month risk of discontinuation was examined using Cox proportional hazards models controlling for gender, psychiatric comorbidities, and pre-ziprasidone utilization of antipsychotics (atypical, conventional, none). **RESULTS:** Mean age of the sample ($n = 1058$) was 38 years; 42% were male. The 6-month risk of discontinuation was significantly greater in patients with a low vs high initial dose ($HR = 1.357$, 95% $CI = 1.070, 1.721$; $p = 0.012$) and trended towards significance when comparing a medium vs high initial dose ($HR = 1.163$, 95% $CI = 0.905, 1.494$; $p = 0.237$). The largest difference in discontinuation rates between dose groups occurred after the first prescription. **CONCLUSIONS:** Patients initiating ziprasidone therapy with an initial dose of at least 120mg/day had better medication adherence compared with those initiating at lower doses. This may reflect improved efficacy at daily doses ≥ 120 mg.

PMH2

GAPS IN ANTIPSYCHOTIC MEDICATION AND RISK OF HOSPITALIZATION FOR THE TREATMENT OF SCHIZOPHRENIA IN MANAGED CARE SETTINGS

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